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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/430,198	10/29/1999	DAVID ZAHNISER	CYM-034	6914

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EXAMINER	
KIM, CHONG R	

ART UNIT	PAPER NUMBER
2623	17

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/430,198	Applicant(s) ZAHNISER ET AL.	
	Examiner Charles Kim	Art Unit 2623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,20,21 and 23-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14,20,21 and 23-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 October 1999* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment and Arguments

1. Applicant's amendment filed on May 3, 2004 has been entered and made of record.

2. Applicant's arguments have been fully considered, but they are not deemed to be persuasive for at least the following reasons.

Applicants argue (page 7) that their claimed invention (claims 1-3, 5, 7-8) differs from the prior art because "there is no suggestion in Gibbs that the location of an area of interest requires any automated verification". The Examiner responds by pointing out that the claim language does not appear to recite this feature.

Applicants further argue (page 7) that "the Examiner merely concluded that it would have been obvious to modify the teachings of Gibbs to perform such verification based on the dimensional error between datum mark measurements without providing any basis as to where a teaching or suggestion of such modification could be found in the prior art." In response to applicant's argument that there is no suggestion to modify the reference, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the suggestion/motivation for modifying the Gibbs reference would have been to provide the

capability of highly accurate locating and relocating of microscope objects of interest in the sample (Gibbs, col. 12, lines 65-68).

Applicants further argue (page 8) that their claimed invention (claims 10-14, 20-21, 23-25) differs from the prior art because "Ortyn suggests that Gibbs can be modified so that it can test the repeatability of its stage movement using datum marks on a calibration slide. There is no suggestion in Ortyn that Gibbs can be modified to verify the location of an area of interest on the actual biological specimen". The Examiner disagrees. Gibbs explains that the location of the area of interest is verified by positioning the datum mark at the center of the microscope's visual field, and pressing the key "GO" **to move the stage** so that the area of interest appears at approximately the same location as when it was originally detected (col. 9, line 60-col. 10, line 14). Ortyn's teaching obtains the "spatial offset" between the determined positions of the datum marks to prevent the system from **moving to an incorrect position** (col. 6, lines 46-52). Ortyn also explains that the measured data is verified if the spatial offset is less than a tolerance value (col. 2, lines 43-48 and col. 6, TABLE 1). Accordingly, Ortyn suggests that Gibbs can be modified to accurately verify the location of an area of interest in the actual biological sample by preventing the stage from moving to an incorrect position during the location of the area of interest, and by verifying the measured data if the "spatial offset" is less than a tolerance value.

Drawings

3. The drawings are objected to because they are not of sufficient quality for publication.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Referring to claim 14, the phrase "coordinate value resulting from spatially locating the mark" in lines 13-14 lacks antecedent basis. It appears that the applicant intended the phrase to read "coordinate value resulting from spatially relocating the mark". Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-3, 5, 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gibbs, U.S. Patent No. 5,000,554 ("Gibbs").

Referring to claim 1, Gibbs discloses a method for verifying a location of an area of interest within a sample, the method comprising:

a. locating a datum (reference) mark on the sample (col. 9, lines 12-29)

b. identifying the area of interest within the sample (col. 9, lines 30-41)

c. determining the location of the area of interest relative to the mark (col. 9, lines 41-46)

d. relocating the datum (col. 9, lines 60-66).

Gibbs further discloses that the location of the area of interest is verified when the area of interest is detected "at approximately the same location as when it was originally detected" (col. 10, lines 1-6). Gibbs fails to explicitly disclose that the location of the area of interest is verified if a dimensional error in locating the datum relative to relocating the datum is less than a tolerance value. However, Gibbs explains that relocating the datum results in a position that is approximate to the position determined originally in locating the datum (col. 9, lines 60-65). The Examiner notes that the word "approximate" is defined by the Webster's dictionary as "nearly correct or exact". Therefore, a dimensional error is an inherent feature in determining an approximate position. Although Gibbs does not explicitly state that the location of the area of interest is verified if the dimensional error is less than a tolerance value, it would have been obvious to modify Gibbs's teachings so that the location of area of interest is verified if the dimensional error is less than a tolerance value, in order to allow the area of interest to be detected on a later occasion at approximately the same location as when it was originally detected (col. 9, line 60-col. 10, line 6), thereby resulting in highly accurate locating and relocating of microscopic objects of interest in the sample slide (col. 12, lines 65-68).

Referring to claim 2, Gibbs further discloses that identification of the area of interest within the sample comprises optically scanning the sample (col. 9, lines 30-35).

Referring to claim 3, Gibbs fails to explicitly disclose that the tolerance value is between about ten microns and one thousand microns. However, Gibbs explains that relocating the datum results in a position that is approximate to the position originally determined in locating the datum, as noted above. Therefore, although Gibbs does not explicitly teach that the tolerance value is between about ten microns and one thousand microns, it would have been obvious to have a tolerance value between ten microns and one thousand microns, in order to minimize the dimensional error and provide a highly accurate locating and relocating of microscopic objects of interest in the sample slide (col. 12, lines 65-68).

Referring to claim 5, Gibbs further discloses that the sample comprises a cytological specimen deposited on a slide (col. 6, lines 20-22).

Referring to claim 7, Gibbs further discloses that the sample is mounted on a stage (col. 4, lines 54-58).

Referring to claim 8, Gibbs fails to explicitly disclose the step of rejecting the sample if the location of the area of interest is not verified. However, Gibbs is concerned with accurately locating and relocating the area of interest in the sample slide (col. 12, lines 65-68). Therefore, it would have been obvious to reject the sample if the location of the area of interest is not verified, since a location of the area of interest that is not verified implies that the area of interest is not accurately located. The ordinary artisan would have been motivated to do so in order to obtain sample slides that include the locations of the area of interest determined accurately, thereby improving the accuracy and efficiency of the examination process.

6. Claims 4, 6, 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Gibbs, U.S. Patent No. 5,000,554 ("Gibbs") and Kamentsky, U.S. Patent No. 5,587,833 ("Kamentsky").

Referring to claim 4, Gibbs fails to disclose the steps of identifying a plurality of areas of interest within the sample and ranking the plurality of areas of interest in an order.

Kamentsky teaches the steps of identifying a plurality of areas of interest within a sample and ranking the plurality of areas of interest in an order (col. 8, lines 4-18).

Gibbs and Kamentsky are both concerned with locating an area of interest within a cytological sample slide. Kamentsky's method saves time and increases efficiency of the re-examination process by providing the Pathologist with the locations of the areas of interest that were considered important during an initial examination (Kamentsky, col. 8, lines 22-39). Therefore, it would have been obvious to include the teachings of Kamentsky in the method of Gibbs, in order to reduce the redundancy of the work required by the Pathologist, thereby enhancing the efficiency of the overall examination process.

Referring to claim 6, Gibbs explains that the sample comprises a blood sample specimen (col. 6, lines 20-22), but fails to explicitly state that the area of interest within the sample comprises an abnormal cell. However, defining an area of interest within a blood sample as an abnormal cell was exceedingly well known in the art. For example, Kamentsky discloses that the area of interest within a blood sample comprises an abnormal cell (col. 1, lines 12-19).

Gibbs and Kamentsky are both concerned with locating an area of interest within a cytological sample slide. Therefore, it would have been obvious to modify the area of interest of Gibbs so that it comprises an abnormal cell, as taught by Kamentsky, in order to utilize the

method for pathological research such as the examination of cancer cells, thereby increasing the flexibility of the system (Kamentsky, col. 1, lines 12-19).

Referring to claim 9, Gibbs fails to teach the step of placing a visible indicator proximate the area of interest identified within the sample.

Kamentsky teaches the step of placing a visible indicator proximate the area of interest identified within the sample (col. 8, lines 15-18).

Gibbs and Kamentsky are both concerned with locating an area of interest within a cytological sample slide. Kamentsky's method saves time and thereby increases efficiency of the re-examination process by providing the Pathologist with visible indicators at the locations of the areas of interest that were considered important during an initial examination (Kamentsky, col. 8, lines 22-39). Therefore, it would have been obvious modify the method of Gibbs, so that a visible indicator is placed proximate the area of interest within the sample, as taught by Kamentsky, in order to reduce the redundancy of the work required by the Pathologist, thereby enhancing the efficiency of the overall examination process.

7. Claims 10-14, 20-21, 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Gibbs, U.S. Patent No. 5,000,554 ("Gibbs") and Ortyn et al., U.S. Patent No. 5,499,097 ("Ortyn").

Referring to claim 10 as best understood, see the discussion of at least claim 1 above. Gibbs discloses a method for verifying a location of an area of interest within a sample, the method comprising:

a. locating a datum (reference) mark on the sample (col. 9, lines 12-29)

b. assigning a reference coordinate value to a location of the mark [col. 9, lines 16-20 and lines 38-46. Note that the position of the datum mark is assigned as the reference position (0, 0), since the x and y coordinates of the detected object is the coordinate position relative to the position of the datum mark, see also col. 2, line 47-col. 3, line 6]

c. identifying the area of interest within the sample (col. 9, lines 30-41)

d. assigning a coordinate value to the location of the area of interest (col. 9, lines 30-46)

e. spatially re-locating the mark (col. 9, lines 60-66).

Gibbs further discloses that a spatial offset exists between the re-located mark relative to the originally located mark, as noted above (claim 1). However, Gibbs fails to explicitly disclose the step of determining a spatial offset value of the relocated mark relative to the reference coordinate value.

Ortyn discloses the step of locating a datum mark on the sample, assigning a reference coordinate value to a location of the mark, and spatially re-locating the mark, thereby determining a spatial offset value of the re-located mark relative to the reference coordinate value (col. 5, line 59-col. 6, line 17). Ortyn further discloses that the measured data is verified (validated) if the spatial offset value is less than a tolerance value (col. 2, lines 45-48 and col. 6, TABLE 1).

Gibbs and Ortyn are both concerned with repeatedly taking measurements utilizing a cytological imaging system (Gibbs, col. 12, lines 65-68, Ortyn, col. 6, lines 14-17). Ortyn's method ensures that the system performs above or beyond the engineered limits of the design

(Ortyn, col. 1, lines 29-31). Therefore, it would have been obvious to combine the teachings of Gibbs and Ortyn, in order to maintain a high level of system performance.

Referring to claim 11, Gibbs further discloses that the step of first locating the datum mark comprises centering the mark in a field of view of an optical instrument (col. 9, lines 12-16).

Referring to claim 12, Gibbs further discloses the step of storing in the memory the coordinate value of the area of interest (col. 2, lines 40-46 and col. 6, lines 26-31).

Referring to claim 13, Gibbs further discloses the steps of:

f. transferring the sample to a review station (col. 6, lines 41-47)

g. locating the datum mark (col. 6, lines 47-52)

h. setting a coordinate system of the review station based on a location of the mark (col. 6, lines 52-68, see also col. 3, lines 1-6).

Referring to claim 14 as best understood, Gibbs discloses a method for verifying an area of interest within a cytological specimen on a slide loaded in an automated cytological imaging, the method comprising:

a. placing the slide within an optical path of the imaging system (col. 9, lines 12-16)

b. centering the datum mark on the slide within a field of view of the imaging system (col. 9, lines 12-16)

c. assigning a reference coordinate value to a location of the mark [col. 9, lines 16-20 and lines 38-46. Note that the position of the datum mark is assigned as the reference position (0, 0), since the x and y coordinates of the detected object is the coordinate position relative to the position of the datum mark, see also col. 2, line 47-col. 3, line 6].

d. storing in memory the reference coordinate value (col. 9, lines 16-20)

e. scanning the slide to identify an area of interest within the sample (col. 9, lines 30-46)

f. centering the area of interest within the field of view of the imaging system (col. 9, lines 38-41)

g. assigning a coordinate value to the area of interest (col. 9, lines 30-45)

h. returning to the reference coordinate value location (col. 9, lines 60-68)

i. spatially re-locating the mark (col. 9, lines 60-68).

Gibbs fails to explicitly disclose the step of comparing the reference coordinate value to a coordinate value resulting from spatially re-locating the mark. However, this feature was exceedingly well known in the art. For example, Ortyn discloses the step of locating a datum mark on the sample, assigning a reference coordinate value to a location of the mark, spatially re-locating the mark, and comparing the reference coordinate value to a coordinate value resulting from spatially re-locating the mark, thereby determining a spatial offset value of the mark (col. 5, line 59-col. 6, line 17). Ortyn further discloses that the measured data is verified (validated) if the spatial offset value is less than a tolerance value (col. 2, lines 45-48 and col. 6, TABLE 1).

Gibbs and Ortyn are both concerned with repeatedly taking measurements utilizing a cytological imaging system (Gibbs, col. 12, lines 65-68, Ortyn, col. 6, lines 14-17). Ortyn's method ensures that the system performs above or beyond the engineered limits of the design (Ortyn, col. 1, lines 29-31). Therefore, it would have been obvious to combine the teachings of Gibbs and Ortyn, in order to maintain a high level of system performance.

Referring to claim 20, see the rejection of at least claim 10 above. Gibbs further discloses an optical system and a stage movable relative to the optical system, at least one of the optical system and the stage being operable to position the sample in an optical path of the optical system (col. 6, lines 20-26).

Referring to claim 21, see the discussion of at least claim 5 above.

Referring to claim 23, Ortyn further discloses that the method is performed while the slide is continuously mounted within the imaging system (col. 5, lines 23-58).

Referring to claims 24 and 25, see the rejections of claims 14 and 23 above.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles Kim whose telephone number is 703-306-4038. The

examiner can normally be reached on Mon thru Thurs 8:30am to 6pm and alternating Fri 9:30am to 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amelia Au can be reached on 703-308-6604. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ck
October 8, 2004

Jon Chang
Primary Examiner